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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 20031106

Application Number: 09/744,002
Filing Date: August 02, 2001
Appellant(s): ANDERSON ET AL.

Jane Massey Licata
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 16, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

Claims 1, 12 and 13 have been amended subsequent to the final rejection.

(4) Status of Amendments After Final

The amendment after final rejection filed on September 16, 2003 has not been entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-13 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

A substantially correct copy of appealed claims appears on pages 1-4 of the Appendix to the appellant's brief. The minor errors are as follows: The second appendix includes the claim amendments which were not entered after final.

(9) Prior Art of Record

Mumenthaler et al. "Automated assignment of simulated and experimental NOESY spectra of proteins by feedback filtering and self correcting distance geometry', J. Mol. Biology, vol. 254(1995) pp. 465-480.

Wallace et al, "Derivation of 3D coordinate templates for searching structural databases: Application to Ser-His-Asp catalytic triads in the serine proteases and lipases", Protein Science, vol 5, (June 1996), pp. 1001-1013.

Farber et al, "Determination of Eukaryotic Protein Coding Regions Using Neural Networks and Information Theory" J. Mol. Biol. vol. 226 (1992), pp. 471-479.

Friedrichs et al, "An automated procedure for the assignment of protein ^{1}HN, ^{15}N, ^{15}Ca, $^{1}H^{\alpha}$, $^{13}C^{\beta}$, and $^{1}H^{\beta}$, resonances", J. Biomolecular NMR, vol. 4 (1990), pp. 703-726.

Holm et al, "DALI : A network tool f or protein structure comparison" , Trends Biotechnol. vol. 85 (1995) pp. 478-480.

Bagby et al, "The button test: A small scale method using microdialysis cells for assessing protein solubility at concentrations suitable for NMR" J. Biomolecular NMR, vol. 10 (1997), pp. 279-282.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by the University of Texas at Galveston campus as evidenced by Mumenthaler et al (J. Mol. Biol. (1995) 254:465-480).

3. The examiner takes official notice that one year before the filing date of this application, the University of Texas at Galveston campus comprised a computer, an NMR facility which had a spectrometer, data collection device, and computer algorithms to analyze the NMR spectra and determine the tertiary structure of the proteins including the NOAH program for automated assignment of NOESY spectra, as well as laboratories for expressing proteins, access to the Wisconsin programs which can parse target polynucleotides, and internet access to the Protein Data Bank and the DALI webserver.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al (Protein Science (1996) 5:1001-1013) in view of Mumenthaler et al (J. Mol. Biol. (1995) 254:465-480).

Wallace teaches a method for determining a biochemical function of a protein or polypeptide domain of unknown function (abstract) comprising: a) identifying a putative polypeptide domain that properly folds into a stable polypeptide domain having a definite three dimensional structure, b) determining the three dimensional structure of the stable polypeptide domain (page 1004-5, subheading “derivation of 3D templates”), c) comparing the determined three dimensional structure to known three dimensional structures in the protein data bank, wherein said comparison identified known homologous three dimensional structures (page 1009, subheading “search for Ser-His-Asp triads in other PDB entries”), d) correlating a biochemical function corresponding to

the identified homologous structure to a biochemical function for the stable polypeptide domain (page 1009, figure 5 and page 1011, columns 1 and 2).

Wallace teaches identification of domains, but arguably does not teach the use of domains of 50 to 300 amino acids in length for comparison purposes. Further Wallace does not teach analysis of the structure by a NOESY-assign process in step (b).

Mumenthaler teaches an automated method of assignment of NOESY spectra and automatic calculation of the three dimensional structure by NMR (see abstract).

. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the 3-D structural alignment and function determination method of Wallace with the NOESY assignment method of Mumenthaler since Mumenthaler states ""We regard our method as a highly practical tool for automatic calculation of three dimensional protein structures from NMR spectra with minimal human interference (abstract)". Thus, an ordinary practitioner would have been motivated to determine the 3D structures used by Wallace for analysis by the automated method of Mumenthaler since the method is a highly practical tool which results "In practice, the work required to assign NOESY spectra is dramatically reduced by applying our automated method (page 466, column 2)".

7. Claims 1-5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al (Protein Science (1996) 5:1001-1013) in view of Mumenthaler et al (J. Mol. Biol. (1995) 254:465-480) and further in view of Farber et al (J. Mol. Biol. (1992) 226:471-479).

Wallace in view of Mumenthaler teach the limitations of claims 1, 5, 6 and 11 as discussed above. Wallace in view of Mumenthaler does not teach a prestep of parsing a database to identify the protein coding regions.

Farber teaches a method of discriminating open reading frames (abstract and pages 472-474).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of Wallace in view of Mumenthaler with the database preparation method of Farber since Farber notes "Simple neural networks predict coding regions in DNA very well when trained on a representation of DNA using single codon frequencies (page 478, column 1)". An ordinary practitioner would have been motivated to combine the method of Wallace in view of Mumenthaler with the protein coding determinations of Farber in order to maximize the usable databases to identify homologous proteins and thereby determine the function of unknown proteins.

8. Claims 1, 5, 6, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al (Protein Science (1996) 5:1001-1013) in view of Mumenthaler et al (J. Mol. Biol. (1995) 254:465-480) and further in view of Friedrichs (J. Biomol. NMR (1994) 4:703-726)

Wallace in view of Mumenthaler teach the limitations of claims 1, 5 and 11 as discussed above. Wallace in view of Mumenthaler determines the three dimensional structure of the stable domain by reference to a protein database and suggests the use of NMR. However, Wallace in view of Holm does not teach the specific NMR characterization techniques nor automated NMR assignments.

Friedrichs teaches determination of the correctness of a protein structure using a variety of NMR spectrometer spectra (page 705) and automated analysis of these spectra using a computer program (pages 708-715). Friedrichs further teaches amide hydrogen exchanges (pages 705 and 708).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the 3-D structural alignment and function determination method of Wallace in view of Mumenthaler with the use of NMR structural determination of Friedrichs since Wallace states "This suggests that the development of databases of 3D templates, such as those that currently exist for protein sequence templates, will help identify the functions of new protein structures as they are determined and pinpoint their functionally important regions (abstract)". Here, Wallace expressly motivates the determination of new protein structures. Motivation to use NMR in this determination is provided by Mumenthaler as discussed above and by Friedrich,

who states "The choice of NMR experiments was based on considerations regarding the sensitivity and resolution of spectra for medium to large-sized proteins (page 720)". Friedrich further motivates the automated assignment of NMR spectra in this determination, noting "Instead of taking weeks, the backbone assignments can be made in one or two days following data acquisition and processing (page 722)". An ordinary practitioner would have been motivated to utilize NMR to determine protein structures in order to sensitively and accurately provide data for 3D determinations and would have been motivated to utilize the automated assignments of Friedrichs in order to minimize the time needed to determine the 3D structure as expressly motivated by Friedrichs.

9. Claims 1, 5, 7, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al (Protein Science (1996) 5:1001-1013) in view of Mumenthaler et al (J. Mol. Biol. (1995) 254:465-480) and further in view of Bagby et al (J. Biomol. NMR (1997) 10:279-282).

Wallace in view of Mumenthaler teach the limitations of claims 1, 5 and 11 as discussed above. Wallace in view of Mumenthaler do not teach the button test for microdialysis and NMR.

Bagby teaches a method for preparing samples for NMR to determine optimal solubilization comprising the steps: a) preparing an array of microdialysis buttons with 5 ul containing at least 1 mM protein (page 280), b) dialyzing each member of the array against a different buffer (page 280), c) analyzing the sample to determine if the protein

remained soluble (page 280) and d) selecting the optimum solubility for NMR (page 280). Bagby expressly notes a lab expressed the desired protein (page 281, column 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the button test of Bagby with the NMR and functional determination method of Wallace in view of Mumenthaler since Bagby states "The button test is an efficient, small scale way of tackling this problem.(page 281, column 1)". An ordinary practitioner would have been motivated to utilize the button test to optimize solubility for NMR since it is expressly noted as efficient and small scale, which reduced time and wasted reagents, which for purified proteins can represent a large investment of time and money.

10. Claims 1, 5 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al (Protein Science (1996) 5:1001-1013) in view of Mumenthaler et al (J. Mol. Biol. (1995) 254:465-480) and further in view of Holm et al (TIBS (1995) 20:478-480).

Wallace in view of Mumenthaler teach the limitations of claims 1, 5 and 11 as discussed above. Wallace in view of Mumenthaler do not teach the use of the DALI program or the protein data bank.

Holm teaches determination of three dimensional structures by crystallography or NMR (page 478, column 3) followed by database analysis using the complete three dimensional structure of the protein including every amino acid by DALI (page 478, column 3 and page 479). Holm exemplifies a comparison between urease and

adenosine deaminase (figure 1) in which the complete three dimensional structures of the 352 amino acid adenosine deaminase protein is compared to the larger urease protein. Holm further shows a comparison which was performed for the Adenovirus type 5 knob domain (see page 478, table 1) which knob domain represents amino acids 386 to 581 of the Adenovirus fiber protein, resulting in a comparison of 195 amino acids, within the claim domain size range.

Further it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the 3-D structural alignment and function determination method of Wallace in view of Mumenthaler with the NMR technique taught by Holm and well known in the art for structure determination purposes and with the use of domains within the range of 50-300 amino acids since Holm teaches screening domains of those sizes. An ordinary practitioner would have been motivated to utilize database analysis of Holm in the method of Wallace since Wallace states "As the number of known protein structures increases, so the need for a 3D equivalent of PROSITE grows with it, especially for likely functions of proteins whose biological role is unknown (page 1001, column 1)". Thus, Wallace expressly notes that there is a need for methods of 3D comparison of proteins in order to determine the biochemical function of unknown proteins. Holm satisfies and answers this need to determine the relationship of unknown to known proteins. Holm states "At the last stages of solving a new protein structure, crystallographers and nuclear magnetic resonance (NMR) spectroscopists are keen to know if their structure represents a unique protein fold or if it has an unexpected structural similarity to a known protein fold. To answer these

questions, the DALI server performs a database search with a new structure against all structures in the Protein Data Bank. (Page 478, column 3)". Thus, Holm expressly notes that the ordinary practitioner in this art is motivated to perform a comparison to determine the relationship of the new protein with proteins present in the database, thereby fulfilling the stated need and motivation of Wallace.

11. Claims 1, 5, 8-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al (Protein Science (1996) 5:1001-1013) in view of Mumenthaler et al (J. Mol. Biol. (1995) 254:465-480) and further in view of Holm et al (TIBS (1995) 20:478-480) and further in view of Farber et al (J. Mol. Biol. (1992) 226:471-479).

Wallace in view of Mumenthaler and further in view of Holm teach the limitations of claims 1, 5 and 8-11 as discussed above. Wallace in view of Mumenthaler and further in view of Holm do not teach the use of parsing programs.

Farber teaches a method of discriminating open reading frames (abstract and pages 472-474).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of Wallace in view of Mumenthaler and further in view of Holm with the database preparation method of Farber since Farber notes "Simple neural networks predict coding regions in DNA very well when trained on a representation of DNA using single codon frequencies (page 478, column 1)". An ordinary practitioner would have been motivated to combine the method of Wallace in view of Mumenthaler and further in view of Holm with the protein coding

determinations of Farber in order to maximize the usable databases to identify homologous proteins and thereby determine the function of unknown proteins.

(11) Response to Argument

Introduction

The claimed invention is drawn to a series of steps routinely performed in biotechnology. The sequence of protein discovery in the post genomic age is to sequence a nucleic acid, to identify the protein coding region and then to analyze the domain to determine the three dimensional structure in order to identify the protein function. This routine process is well laid out in the Wallace Abstract, which states (emphasis added):

> "**It is well established that sequence templates (e.g., PROSITE) and databases are powerful tools for identifying biological function and tertiary structure for an unknown protein sequence**. Here we describe a method for automatically deriving 3D templates from the protein structures deposited in the Brookhaven Protein Data Bank. As an example, we describe a template derived for the Ser-His-Asp catalytic triad found in the serine proteases and triacylglycerol lipases. We find that the resultant template provides a highly selective tool for automatically differentiating between catalytic and noncatalytic Ser-His-Asp associations. When applied to nonproteolytic proteins, the template picks out two "non-esterase" catalytic triads that may be of biological relevant. This suggests that the development of databases of 3D templates, such as those that currently exist for protein sequence templates, will help **identify the functions of new protein structures** as they are determined and pinpoint their functionally important regions"

So Wallace expressly teaches the well established, routine, and entirely ordinary idea that new sequences are searched for sequence patterns towards the goal of determining the function of the protein. These claims simply write these routine elements, ordinarily performed by the routine scientist, but ordinarily separated by routineer into the least publishable unit. Further, many of these steps, particularly the

step of parsing the unknown nucleic acid into its open reading frames, are so routine, that they are not listed in scientific publications.

Priority

Appellant first argues that the priority should be granted for the current claims to 09/181,601. It appears that Applicant is mixing up two different priority issues. The case is a Continuation in Part, and this type of filing is, of course, permissible. Appellant is also correct that such a CIP filing may add matter not disclosed in the parent application. Appellant further argues that the parent specification provides support for the claim limitation of a "NOESY-assign process" because this is one means of "determining the three dimensional structure of the stable polypeptide domain".

However, the issue of priority of the claims as distinct from the simple priority claim, particularly as regards descriptive support, is not answered solely by the filing of a CIP. As MPEP 2133.01 notes "When applicant files a continuation-in-part whose claims are not supported by the parent application, the effective filing date is the filing date of the child CIP." In this case, as noted in the priority section in the final rejection, parent application 09/181,601 completely lacks any support for the CLAIM LIMITATION of a "NOESY-assign process". A word search of the specification fails to find the use of this term at all in the specification. Appellant appears to agree to this point by stating that "The limitation of 'NOESY-assign process', which was added to claim 1 of this continuation in part application (see page 6 of brief)." This statement indicates that the limitation was added in the CIP and was not present in the parent application. The general description of "determining three dimensional structure of the stable polypeptide

domain" does not provide support for the specific limitation of a "NOESY-assign process". Thus, for purposes of the prior art, since the parent application does not have descriptive support for the term "NOESY assign process", the effective filing date for these claims is the filing date of the current application.

102(b) rejection

Appellant then argues that the 102(b) rejection should fall because the proteins being analyzed by the apparatus are of "known" as versus "unknown" function and because there is no teaching of a parsing step. First, as noted above, this after final amendment was not entered, since it was not timely filed and does not simplify the issues. Appellant does not traverse the fact that the University of Texas campus, as evidenced by Mumenthaler et al (1995), comprises each and every structural limitation of the claimed product. Appellant simply argues that certain intended use recitations are not met by the rejection. As noted in the rejection, the university has access to programs which can parse the nucleic acid sequence, programs which have been available since the early 1970s. As noted in MPEP 2144.03, since Appellant did not traverse the factual existence of the programs, including the Wisconsin programs such as GCG at the University of Texas campus, and in fact still does not traverse the existence of all of the structural elements at the University of Texas campus, this is taken as admitted prior art which cannot be traversed.

Appellant then argues that the prior art does not teach the analysis of proteins of "unknown" function because the protein of Mumenthaler was known. However, in a product claim, such as the integrated system of claim 12, the status of the protein as

either "known" or "unknown" is not patentably relevant. As MPEP 2111.02 notes "Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." It is clear that a structural difference must exist between the claimed integrated system and the prior art to overcome the rejection and not simply a difference in the intended use. Here, there is no structural difference. It is uncontraverted that the University of Texas, prior to the date of invention, (as well as every other major research university, the National Institutes of Health, and many major pharmaceutical companies), comprised an integrated system with computer algorithms for parsing, labs for expressing proteins, NMR spectrometers with data collection devices, computers, Mumenthaler evidences that the algorithm that assigns spin resonances was on the University of Texas campus, and internet connections which could access Genbank and the Protein Databank, which had algorithms for analyzing homology and determining tertiary structure. Therefore, all of the structural elements existed in the prior art in a single "integrated system." The intended use does not distinguish the claimed system from the prior art and this rejection should be maintained, or the claim will render the University of Texas, and many other institutions, instant infringers.

103 Rejections

Appellant initially argues that the rejection, and Wallace in particular, does not teach the use of a domain of 50 to 300 amino acids. This argument is not correct on

several levels. First, Wallace teaches formation of 3D templates based upon secondary structure, stating on page 1004 that "The second of our two data sets was a representative set of protein structures in the PDB. The 3D templates derived from the enzyme data set were applied to this second data set to see if any Ser-His-Asp triplets, in the catalytic conformation, are present in any other proteins. The second data set was a set of unique protein chains, including homologues, but excluding identical or trivially different chains such as single-residue mutants. It was compiled by extracting protein chains from the PDB such that no two had a sequence identity greater than 95%. The resultant 639 protein chains are listed in Table 2." The proteins listed in Table 2 are all part of the Wallace data set and were all analyzed using the Wallace method. All of these proteins are larger than 50 amino acids. The argument by Appellant that the "triad" consists of only three amino acids ignores both what Wallace actually did and what a protein structure comprises. Wallace analyzed the full protein structures of these proteins to determine the three amino acids involved in the actual catalysis. A protein structure such as the catalytic triad of Wallace does not represent three amino acids lost in space, but represents three amino acids, embedded in a context. That context is provided by all of the other amino acids in the protein chain. What Wallace did was to analyze the three amino acids in the context of the folds and three dimensional structure and context provided by all of the remaining amino acids in the protein. Without that context, and those other amino acids, the method of Wallace would be nonsensical.

Second, the three amino acids Ser, His and Asp occur in nearly every protein of appreciable length, but only form the catalytic triad necessary for the protease function when the remaining amino acids of the protein place these three amino acids in the proper positions, the proper context, to result in protease function. So when Wallace performs the analysis, Wallace is expressly using the entire protein sequence imposed by the each of the amino acids in relationship to one another to determine the catalytic triad. Wallace expressly teaches that in the quote above, where the data sets were chosen from the PDB. Wallace does teach that only a part of the data set comprising less than the entire protein was used. At page 1004, Wallace teaches the use of the entire data set representing the entire protein sequence.

Therefore, contrary to Appellant's argument, Wallace does not teach away from the use of 50 to 300 amino acid domains but rather expressly teaches the use of large amino acid domains such as those found in the serine proteases. Appellant mischaracterizes the Wallace teaching at page 1002, by arguing that the use of the Ser-His-Asp catalytic triad was limited to the use of those three amino acids without the context. As indicated above, such an analysis would yield nonsense. The 3D template must incorporate the structural elements imposed by the rest of the protein or the template will not yield any meaningful results. This context provides the remaining amino acids. This context can be seen throughout the Wallace paper and especially in figure 7, where the entire structure of the proteins is diagrammatically shown, with standard secondary structural elements substituting for some of the amino acids such as beta sheets and alpha helical barrels.

Appellant then argues that Wallace does not teach identification of a protein of unknown structure. This is simply incorrect, as Wallace states "It is well established that sequence templates (e.g., PROSITE) and databases are powerful tools for identifying biological function and tertiary structure for an **unknown protein** sequence (see abstract). This directly contradicts Appellant's assertion that Wallace does not teach identification of an unknown protein. Wallace expressly teaches and recognizes tools for the identification of biological function of unknown proteins.

Appellant then argues there is no motivation to combine the references. In this case, specific motivation is cited in each of the rejections relying upon Mumenthaler and Farber. For example, an ordinary practitioner would have been motivated to determine the 3D structures used by Wallace for analysis by the automated method of Mumenthaler since the method is a highly practical tool which results "In practice, the work required to assign NOESY spectra is dramatically reduced by applying our automated method (page 466, column 2)". This represents a motivation to combine the references, since the ordinary practitioner would reduce work required to develop data for analysis by the Wallace method in order to identify unknown protein structures as expressly taught by Wallace.

Appellant raises two other points. First, Appellant argues that Farber is in an area distinct from that of Wallace and Holm. This argument is simply incorrect and untrue. It is standard and beyond standard for any molecular biologist to utilize computers in the analysis of DNA sequences that encode proteins. That this is a recognized step in analysis of nucleic acids is shown by Farber, who states at page

478, column 2 "Achievement of sufficiently high accuracies on short fragment lengths is critical for a computational means of finding coding regions in unannotated DNA sequences such as those arising from the mega-base sequencing efforts of the Human Genome Project." This expressly shows that the determination of the protein coding regions is linked to the sequencing and protein analysis efforts of the Human Genome Project.

Second, is there motivation to combine the references. Farber teaches that the ordinary biochemist, after performing mega base sequencing, would wish to find coding regions by computational means. An ordinary practitioner would therefore be motivated to apply the method of Farber to identify the proteins present in the sequenced human genome. Once that practitioner determined the protein sequence, Wallace teaches that the ordinary practitioner would wish to identify the function of unknown coding regions, "will help identify the functions of new protein structures as they are determined and pinpoint their functionally important regions (abstract)". So there is significant motivation to integrate these methods in order to take an unknown nucleic acid sequence and yield the result desired by Wallace, of identifying the function of the protein structure.

Appellant concludes by arguing that there is no reasonable expectation of success. The legal standard for "reasonable expectation of success" is provided by caselaw and is summarized in MPEP 2144.08, which notes "obviousness does not require absolute predictability, only a reasonable expectation of success; i.e. , a reasonable expectation of obtaining similar properties. See , e.g. , In re O'Farrell , 853

F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988)." In this factual case, there is express teaching of Wallace and Holm of how to perform the functional analysis of proteins by comparing the 3D structures. Wallace shows successful performance of the method. Mumenthaler teaches the successful use of the NOESY-assign program for NMR analysis. There is further evidence as shown by Farber that 99.4% (see page 478) of the coding sequences will be correctly parsed by his method. This sufficient for a reasonable expectation of success. The MPEP cites In re O'Farrell, which notes regarding "obvious to try" at page 1682, that,

> "In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. E.g ., In re Geiger , 815 F.2d at 688, 2 USPQ2d at 1278; Novo Industri A/S v. Travenol Laboratories, Inc ., 677 F.2d 1202, 1208, 215 USPQ 412, 417 (7th Cir. 1982); In re Yates , 663 F.2d 1054, 1057, 211 USPQ 1149, 1151 (CCPA 1981); In re Antonie , 559 F.2d at 621, 195 USPQ at 8-9. In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. In re Dow Chemical Co ., 837 F.2d, 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1985); Hybritech, Inc. v. Monoclonal Antibodies, Inc ., 802 F.2d 1367, 1380, 231 USPQ 81, 90-91 (Fed. Cir. 1 986), cert. denied , 107 S.Ct. 1606 (1987); In re Tomlinson ; 363 F.2d 928, 931, 150 USPQ 623, 626 (CCPA 1966).

The court in O'Farrell then, affirming the rejection, notes " Neither of these situations applies here." For the instant case, it is clear that neither situations applies here either. This is not a situation where the prior art suggests varying a variety of parameters, since the prior art of Wallace and Farber teach specific methods which specifically function and are shown to yield working results. This is also not a situation where only general guidance was given. The prior art provides specific guidance directing in how to parse and analyze proteins.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Jeffrey Fredman
Primary Examiner
Art Unit 1634

November 7, 2003

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